Limited information was available linking disease severity to QoL. **CONCLUSIONS:** In studies of patients receiving treatment for recurrent or metastatic SCCHN, median OS did not differ systematically among populations receiving regimens containing cetuximab, docetaxel, methotrexate, or paclitaxel. Among platinum-refractory patients, no treatment was identified as having demonstrated significant improvements in QoL.

PCN26

LIPEGFILGRASTIM FOR REDUCTION OF CHEMOTHERAPY-INDUCED NEUTROPENIA RELATED EVENTS: A META-ANALYSIS

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OBJECTIVES: The purpose of the current meta-analysis was to compare the efficacy of lipegfilgrastim (LIP) to pegfilgrastim (PEG) and filgrastim (FIL). **METHODS:** EMBASE was searched for head-to-head trials examining the efficacy of LIP, PEG, or FIL. Outcomes included incidence of febrile neutropenia (FN), incidence of severe neutropenia (SN), duration of SN (DSN), and time to recovery of absolute neutrophil count (ANC). Direct comparisons of SN/FN between LIP and PEG were made using random-effects models estimating relative risk (RR). No trials directly compared LIP and FIL; indirect comparisons were made with PEG or placebo/no treatment (PLA) as the common comparator. For DSN/ANC recovery, generic inverse variance methods were employed. **RESULTS:** Sixty-five studies were identified and 24 were included after full-text review and quality assessment via PRISMA criteria. Over all treatment cycles, LIP was non-inferior to PEG for risk of FN (RR 0.34, 95% CI: 0.05, 2.14). The indirect estimate of FN for LIP versus FIL was also non-significant (RR 0.22, 95% CI: 0.03, 1.51). For SN during cycle 1, LIP had a RR of 0.80 (95% CI: 0.63, 1.03) versus PEG and 0.79 (95% CI: 0.61, 1.03) versus FIL. For subsequent cycles, the RR was 0.53 (95% CI: 0.35, 0.79) LIP versus PEG and 0.45 (95% CI: 0.27, 0.75) versus FIL. Time to ANC recovery was significant: -1.75 days (95% CI: -2.61, -0.90) for LIP versus PEG and -1.88 days (95% CI: -2.82, -0.95) for LIP versus FIL. No comparions were significant for DSN. **CONCLUSIONS:** LIP showed non-inferiority to PEG for risk of at least one FN episode and SN in cycle 1. LIP was more effective than both PEG and FIL for prevention of SN in cycles 2-4 and reduced ANC recovery time. However for DSN differences were not significant. These results suggest that LIP is a possibly more effective treatment.

PCN27

COMPARATIVE EFFECTIVENESS OF GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSF) FOR REDUCING INCIDENCE OF FEBRILE NEUTROPENIA (FN) –RELATED HOSPITALIZATION: A RETROSPECTIVE COHORT STUDY USING GERMAN CLAIMS DATA

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OBJECTIVES: Effectiveness of daily G-CSF prophylaxis can be decreased when given in short courses. The objective was to determine the difference in odds of FN-related hospitalizations with once per cycle G-CSF (pegfilgrastim) prophylaxis compared to daily G-CSF (filgrastim/lenograstim) prophylaxis for patients receiving high/intermediate FN-risk chemotherapy for breast cancer or Non-Hodgkin lymphoma (NHL). **METHODS:** This retrospective cohort study used claims data from the Health Research Institute research database with <4 million insured individuals in Germany. Patients receiving first-line, high/intermediate FN-risk chemotherapy for breast cancer or NHL from January 1, 2009 to December 31, 2013 were included and those cycles with G-CSF administration initiated ≤5 days following chemotherapy were assessed. G-CSF types were identified by ATC codes and FN-related hospitalizations within each cycle were identified by ICD-10-GM codes with a primary/secondary diagnosis of neutropenia (D70.1*, D70.7). Odds ratios (OR) for FN-related hospitalization and 95% confidence intervals (CI) were estimated with generalized estimating equation models and adjusted for age, gender, tumour type, metastatic status, cycle number, chemotherapy FN-risk and history of anaemia and surgery. **RESULTS:** In total, 2,278 patients representing 7,918 cycles (6316 pegfilgrastim, 1602 daily G-CSF) were included in the analysis; 2,037 (89%) patients had breast cancer and 241 (11%) had NHL. More than half of patients receiving pegfilgrastim prophylaxis initiated it in cycle 1, primary prophylaxis, (56%) whereas 37% of patients receiving daily G-CSF prophylaxis initiated it in cycle 1. Three-quarters of patients receiving daily G-CSF were prescribed 5 or less doses in at least one cycle. Cycles with prophylactic daily G-CSF were associated with an increased risk of FN-related hospitalisations (adjusted OR=2.19, 95% CI: 1.41-3.39; p-value < .001) in comparison to cycles with prophylactic pegfilgrastim. **CONCLUSIONS:** This comparative effectiveness analysis showed a significantly higher likelihood of FN-related hospitalizations in cycles with daily G-CSF prophylaxis versus those with pegfilgrastim prophylaxis.

PCN28

ANALYSIS OF ERIBULIN MESYLATE DOSING MODIFICATIONS IMPACT ON ADMINISTRATION PERSISTENCE IN PATIENTS WITH METASTATIC BREAST CANCER (MBC)

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OBJECTIVES: Eribulin mesylate is a microtubule inhibitor FDA approved for patients with MBC after treatment with at least two prior chemotherapeutic regimens. The recommended dose of eribulin is 1.4 mg/m2 administered on Days 1 and 8 of a 21-day cycle with options for dose modification (dose reduction/dose delay) based on severity and duration of specific toxicities. Recent studies, limited to the clinical trial setting, have shown dose modifications lead to greater treatment persistence and improved patient outcomes. This study utilized real-world claims data to evaluate the relationship between dose modifications and persistence among patients that receive 5 or more administrations. **METHODS:** Using data from the Cardinal Health Specialty Solutions Revenue Cycle Management medical claims database, 267 patients who received 5 or more eribulin administrations and completed therapy between May 2014 and April 2015 were included in the analyses. The Relative Dose Intensity (RDI) methodology compared the intensity of dose received per day of treatment against expected dose (recommended dose) intensity. RDI values and total number of eribulin administrations were calculated for each patient based on the presence or absence of either dose reduction and/or dose delay. Data was analyzed using an independent samples t-test. **RESULTS:** An analysis of patient distribution revealed the mean number of eribulin administrations was 13.4 with a mean RDI of 85%. Persistence was statistically higher in patients that had eribulin therapy managed through dose delay and dose reduction strategies. Patients with no modification (100% RDI) received an average of 8.1 eribulin administrations. Patients with dose modification (81% RDI) received an average of 14.5 eribulin administrations (p <0.001). **CONCLUSIONS:** Management of eribulin therapy in patients with MBC via dose delay and/or reduction resulted in a statistically significant increase in persistence among responding patients.

PCN29

A SYSTEMATIC LITERATURE REVIEW TO IDENTIFY AND COMPARE CLINICAL TRIALS EVALUATING NOVEL THERAPEUTIC AGENTS IN POST-GEMCITABINE ADVANCED PANCREATIC CANCER

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OBJECTIVES: There is currently no standard of care for patients with advanced pancreatic cancer (APC), including locally advanced and metastatic disease, who progressed following first-line therapy. Available treatment options have been limited by a lack of therapeutic breakthroughs, and primarily utilize different combinations and dosing schedules of established chemotherapeutic agents. The current review assesses the relative efficacy of new therapeutic agents tested, alone or in combination, since 2003 in patients with APC who progressed following gemcitabine-based therapy. **METHODS:** A systematic literature review was performed in PubMed/MEDLINE, EMBASE and ASCO meeting abstracts between January 2003 and June 2015. This review identified randomized controlled trials (RCTs) and single-arm trials evaluating new post-gemcitabine regimens in patients with APC. **RESULTS:** A total of 34 trials, evaluating 1263 patients, were identified. New agents that have been tested include small molecules (24 trials), antibodies (3 trials), nanotherapeutics (4 trials), and immunotherapies (3 trials). The majority of studies were small, single-arm trials (n=27). RCTs (n=7, enrolling 835 patients) were further investigated as they represent the standard for demonstrating therapeutic efficacy. At the time of analysis, the only Phase 3 RCT to evaluate a new therapeutic agent in post-gemcitabine APC was the NAPOLI-1 trial (nanoliposomal irinotecan (MM-398, nal-IRI) + 5-fluorouracil and leucovorin (5FU/LV) versus 5FU/LV), which was a large, global study that demonstrated a statistically significant improvement in overall survival in patients with metastatic disease, including heavily-pretreated patients. **CONCLUSIONS:** The present review highlights the limited number of RCTs evaluating new therapeutic agents in patients with APC who previously received gemcitabine. Most new agents fail to be evaluated beyond small, uncontrolled trials of APC. Despite much research in this difficult-to-treat patient population with high unmet medical need, only one Phase 3 RCT of a new agent (nal-IRI) + 5FU/LV demonstrated significant improvement in overall survival in patients with APC who had progressed following gemcitabine-based therapy.

PCN30

A REAL-WORLD ANALYSIS OF KOREAN NATION-WIDE DATABASE: PATTERN, ADHERENCE, AND ASSOCIATED HEATLHCARE COSTS OF IMATINIB AMONG PATIENTS WITH CHRONIC MYELOID LEUKEMIA

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OBJECTIVES: This study aimed to determine the demographic features, treatment pattern, medication adherence, survival rates and associated healthcare costs in patients with newly diagnosed Ph+ CML from Korean National health Insurance (NHI) claims database **METHODS:** We conducted a longitudinal analysis of patients with newly diagnosed Ph+ CML (ICD-10: C92.1) and started treatment with imatinib in 2005 enrolled in the Korean NHI program. Patients were excluded if they had ≥ 1 claim with a diagnosis of other cancer within one year before diagnosis of CML. All data were retrieved from the NHI Database provided by National Health Insurance Corporation in Korea **RESULTS:** In the study, a total of 8,986 patients with a diagnosis of Ph+ CML between January 1, 2004 and December 31, 2013 were identified. Among them, our study population consisted 268 patients (mean age: 46.4±14.7 years, male: 57.4%) with the diagnosis of CML in 2005. The majority of patients (75.9%) initiated imatinib therapy at a starting dose was 400mg/day. With over 7 years of follow-up data, based on the 180-day gap definition of discontinuation, 33 (11.7%) patient was discontinued and discontinuation period was 395.4±137.2 days (range: 189-1,023). Overall, 44.3% (n=125) of patients were defined as Good Medication Possession Ratio (MPR) (≥ 90%) and 19.2% (n=54) were as Poor MPR (<70%). During follow-up period, 69 patients (24.5%) were deceased and the time to death for them was 3.18 years (1,159.5 ± 845.1 days) after initiation of imatinib. Patients with Good MPR had significantly higher survival compared to patients with Poor MPR (p<0.001). **CONCLUSIONS:** In a retrospective assessment of a large cohort of patients with CP-CML treated with imatinib, we have shown that nonadherence to therapy is important factor for survival. Adherence to therapy must be included as an important evaluation parameter in all future studies of CML

PCN31

EROLTINIB PLUS GEMCITABINE COMPARED WITH GEMCITABINE MONOTHERAPY IN PATIENTS WITH PANCREATIC CANCER: A REAL-WORLD ANALYSIS OF KOREAN NATIONA-WIDE DATABASE

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OBJECTIVES: This national population-based retrospective study aimed to evaluate the relative effectiveness of adding erlotinib to gemcitabine with pancreatic cancer patients compared to gemcitabine in real clinical practice. **METHODS:** Patients was identified retrospectively using Korean National Health Insurance claims database who pancreatic cancer (ICD-10: C25) who initiated chemotherapy with gemcitabine or erlotinib between January 1, 2007 and December 31, 2012. To be included in the study population, patients were required to have a history of intervention for histologic or cytologic diagnosis within one year before chemotherapy. For homogeneity, patients were excluded if they have diagnosed with other cancers where gemcitabine is indicated or prior radiotherapy or surgical treatment. **RESULTS:** A total of 4,267 patients were included. Overall survival was not significantly longer in patients treated with gemcitabine/erlotinib (median 6.77 months for gemcitabine/erlotinib vs. 6.68 months for gemcitabine, p=0.0977). One-year survival rate was also not significantly different (27.0% vs. 27.3%; p=0.5988). Based on this relative effectiveness, incremental cost per life year gained over gemcitabine was estimated at USD 70,843.64 for gemcitabine plus erlotinib. **CONCLUSIONS:** Combination of gemcitabine/erlotinib of advanced pancreatic cancer is not more effective than gemcitabine monotherapy in a real-world setting. It does not provide reasonable cost-effectiveness over gemcitabine alone, and reimbursement strategies for pancreatic cancer in Korea could be reconsidered.

PCN32

THE RELATIVE EFFICACY AND SAFETY OF TREATMENTS IN SECOND-LINE MANAGEMENT OF CHRONIC MYELOID LEUKAEMIA: SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS FEASIBILITY STUDY

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OBJECTIVES: To assess relative efficacy and safety of second-line treatments in chronic myeloid leukaemia (CML), a systematic review (SR) and network meta-analysis (NMA) feasibility study were conducted. **METHODS:** A SR was conducted in January 2015 (Embase, MEDLINE, Cochrane Library, Clintrials.gov and conferences) to identify comparative trials evaluating treatment outcomes in patients with CML previously treated with tyrosine kinase inhibitors. Eligible studies were examined to assess NMA feasibility. **RESULTS:** Twenty-three publications relating to six randomised controlled trials (RCTs) on second-line treatment met the eligibility criteria. Included studies compared either nilotinib (n=3) or dasatinib (n=1) with imatinib, or studied dasatinib at alternative doses (n=2). No comparative bosutinib or ponatinib studies were identified. Efficacy outcomes were reported using various definitions and different time points. Compared with nilotinib, significantly fewer imatinib treated patients with complete cytogenetic response (CCyR) at baseline, achieved complete molecular response (CMR) (23% vs 11%, p=0.02) by 12 and confirmed CMR (22.1% vs 8.7%, p=0.0087) by 24 months and in patients without major molecular response (MMR) at baseline, MMR by 12 (75% vs 36%, p=0.006) and 24 (83.3% vs 53.6%, p=0.0342) months. Compared with imatinib, significantly more dasatinib patients achieved CCyR (16% vs 40%, p=0.004; 18% vs 44%, p=0.0025), MMR (4% vs 16%, p=0.038; 12% vs 29%, p=0.028) and complete haematologic response (82% vs 93%, p=0.034; 82% vs 93%, p=0.0341) at 15 and 24 months, respectively. Interpretation of safety data was inconclusive due to its limited availability and treatment exposure differences. Even considering prospective non-RCTs, NMA was not feasible due to missing network links, significant differences between trial populations, and varying follow-up times. **CONCLUSIONS:** Review of all published comparative studies on second-line treatment of CML confirms that, based on direct efficacy results, dasatinib and nilotinib are the second line agents of choice. NMA comparing nilotinib and dasatinib was not feasible.

PCN33

MATCHING-ADJUSTED INDIRECT TREATMENT COMPARISON AND SURVIVAL EXTRAPOLATION IN RADIOIODINE-REFRACTORY DIFFERENTIATED THYROID CANCER (RAI-REFRACTORY DTC): UPDATED ANALYSIS

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OBJECTIVES: Indirect treatment comparisons (ITCs) are important when evaluating comparative-effectiveness in absence of head-to-head clinical trials. Classic ITCs can lead to biased results due to differences in patient populations and trial designs. These differences can be corrected for by using matching-adjusted-ITC (MAIC) technique. Furthermore, extrapolation of survival data beyond clinical trial results may be required for economic evaluations. The objective of this research was to compare lenvatinib and sorafenib in patients with RAI-Refractory DTC using MAIC and survival extrapolation techniques. This analysis is an update to the MAIC published previously using a later data cut-off date for both drugs. **METHODS:** Mean overall-survival (OS) and progression-free survival (PFS) outcomes were estimated by weighting patient-level data based on baseline characteristics from individual phase III trials using logistic regression. Classic ITC was performed before and after adjustment. Cross-over correction was also applied. Extrapolation of OS and PFS was performed using proportional hazard, accelerated time failure, individual parametric models and piecewise models. Results were presented as hazard-ratios (HR) with confidence-intervals (CI). **RESULTS:** Unadjusted ITCs for Lenvatinib vs. placebo were 0.545(0.350; 0.830) for OS and 0.213(0.158; 0.288) for PFS. MAIC provided statistically significant estimates of 0.505(0.300; 0.820) for OS and 0.227(0.159; 0.326) for PFS vs. placebo. Unadjusted ITCs vs. sorafenib were 0.790(0.453; 1.379) and 0.361(0.244; 0.534) respectively for OS and PFS; while MAIC results were 0.732(0.396; 1.352) and 0.385(0.248; 0.596) respectively for OS and PFS. Survival extrapolation provided estimates of 8 month of additional OS gain for Lenvatinib vs. sorafenib, with MAIC extrapolation showing largest gain and a good model fit. **CONCLUSIONS:** This analysis demonstrated that in absence of head-to-head trials, MAIC is an important methodology to adjust for population and trial differences, especially in orphan diseases where limited data are available. MAIC can increase reliability of comparative-effectiveness data and support payers decision making.

PCN34

A DESCRIPTION OF REAL-WORLD TREATMENT WITH ABIRATERONE ACETATE IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER PATIENTS IN THE POST-CHEMOTHERAPY SETTING IN FRANCE AND THE NETHERLANDS

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OBJECTIVES: In the COU-AA-301 trial, abiraterone acetate with low-dose prednisone (AA) was found to extend survival in metastatic castrate resistant prostate cancer (mCRPC) patients progressing after docetaxel chemotherapy compared to placebo with low-dose prednisone. This study aimed to evaluate AA treatment duration in routine clinical practice in mCRPC patients in four European countries. Treatment sequencing and survival data were assessed to place the treatment duration into context. Results for France and the Netherlands are reported. **METHODS:** The study was designed as a retrospective chart review. Patients were identified through treating oncologists and urologists. Eligible mCRPC patients were aged ≥18 years, previously treated with docetaxel and naïve to prior AA treatment. Baseline patient characteristics were described using summary statistics. Kaplan-Meier survival analyses were performed for AA treatment duration, overall survival (OS) and time to prostate-specific antigen (PSA) progression endpoints. **RESULTS:** A total of 68 physicians (France and the Netherlands) reported data on 269 mCRPC patients treated with AA. Median PSA (ng/mL) of patients from France and the Netherlands at baseline were 56.0 (interquartile range [IQR]: 28.0-120.0) and 174.5 (IQR: 69.5-371.5), respectively. The median time (months) between mCRPC diagnosis and AA initiation was 12.6 (IQR: 7.0-27.2) in France and 18.3 (IQR: 9.6-30.2) in the Netherlands. Median (months) AA treatment duration, median OS and median time to PSA progression in France was 11.3 (95% confidence interval [95%CI]: 8.3-13.7), 21.6 (95%CI: 14.5-.) and 13.8 (95%CI: 11.0-14.7), respectively. In the Netherlands, it was 4.9 (95%CI: 3.4-6.4), 11.0 (95%CI: 7.3-13.0) and 4.9 (95%CI: 3.0-7.3), respectively. **CONCLUSIONS:** Here we describe the real-world treatment of mCRPC patients receiving AA in the post-chemotherapy setting in two EU countries. This study suggests that initiating AA earlier in the post chemotherapy mCRPC setting may result in better health outcomes.

PCN35

REAL-WORLD ANALYSIS OF TYROSIN KINASE INHIBITOR TREATEMNT PATTERNS AMONG PATIENTS WITH CHRONIC MYELOID LEUKEMIA IN KOREA

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OBJECTIVES: To compare adherence, persistence and switching pattern of tyrosin kinase inhibitor (TKIs) imatinib, dasatinib, and nilotinib in patients with newly diagnosed Ph+ CML from Korean national health insurance (NHI) claims database. **METHODS:** Adults newly diagnosed Ph+ CML (ICD-10: C92.1) patients with imatinib, dasatinib, or nilotininb prescription claims between January 1, 2012 and December 31, 2012 were identified form the NHI claims database. The first day of TKI treatment following Ph+ CML diagnosis was defined as the index date. Adherence was measured using Medication possession ratio (MPR) (Poor MPR: <70%, Good MPR ≥ 90%). Duration of TKI use was determined based on a gap in TKI of ≥ 180 consecutive days after TKI initiation or switch to another TKI within the 180-day window. **RESULTS:** A total of 304 patients were identified. The 184imatinib patients, the 70 dasatinib patients, and 51 nilotinib patients were similar in mean age, gender and comorbidity at baseline. Based on the 180-day gap definition of discontinuation, it was not significantly different. Mean MPR (imatinib 89.1%, dasatinib 91.2%, nilotinib 91.6%, p-value=0.4763) and persistency (imatinib 78.7%, dasatinib 88.5%, nilotinib 95.3%, p-value=0.411) was also not significantly different among three groups. However, switch to second TKI therapy from index TKI in imatinib group was significantly higher than dasatinib and nilotinib (p<0.001). Patients with Good MPR showed higher survival rate (p=0.0039) and patients who do not switch to other TKIs showed higher survival rate (p=0.0040). **CONCLUSIONS:** In a retrospective assessment of patients with CP-CML treated with imatinib, dasatinib and nilotinib, using NHI claims data have shown that imatinib was used more frequently than other TKI in the first-line setting. Furthermore adherence and discontinuation was not different among patients receiving TKI. It would be needed to follow up how treatment decisions for patients with CML are changed over time in routine clinical practice in Korea

PCN36

NEW DRUGS IN ADVANCED MELANOMA: DISPARITIES IN REQUIREMENTS FOR POST-LAUNCH REAL-WORD EVIDENCE IN EUROPE

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OBJECTIVES: To determine country-specific requirements for real-world evidence (RWE) in Europe to support ongoing market access for new drugs to treat advanced melanoma. General perception suggests that RWE is crucial for demonstrating long-term value of innovative products. However, it is unclear how these perceptions correlate with absolute requirements of reimbursement agencies. **METHODS:** We reviewed published health technology assessments (HTAs) and reimbursement agency web sites for feasible data sources for melanoma RWE generation and guidance on collecting RWE in Europe. We also performed a pragmatic review of peer-reviewed literature to identify examples of published RWE in melanoma, and sought views of market access specialists from a global pharmaceutical com-